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NOTICE OF ALLOWANCE AND FEE(S) DUE

38834 7590 02/23/2010

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

EXAMINER

GOON, SCARLETT Y

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 02/23/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,694

11/01/2005

Tetsushi Taguchi

052203

7280

TITLE OF INVENTION: BIOLOGICAL LOW-MOLECULAR-WEIGHT DERIVATIVES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	05/24/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
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or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

38834 7590 02/23/2010

WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP
1250 CONNECTICUT AVENUE, NW
SUITE 700
WASHINGTON, DC 20036

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,694 11/01/2005 Tetsushi Taguchi 052203 7280

TITLE OF INVENTION: BIOLOGICAL LOW-MOLECULAR-WEIGHT DERIVATIVES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
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nonprovisional NO \$1510 \$300 \$0 \$1810 05/24/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
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GOON, SCARLETT Y 1623 530-402000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,694	11/01/2005	Tetsushi Taguchi	052203	7280
38834	7590	02/23/2010	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			GOON, SCARLETT Y	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 02/23/2010				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 288 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 288 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/527,694	TAGUCHI ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 18 November 2009.
2. ☒ The allowed claim(s) is/are 15 and 16.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

/SCARLETT GOON/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

On 15 January 2010, a proposed amendment in condition for allowance was discussed with Mr. Shuji Yoshizaki in a telephone interview. Authorization for this examiner's amendment was given in a telephone interview with Mr. Shuji Yoshizaki on 2 February 2010.

The application has been amended as follows:

- Claims 15 and 16 have been amended as listed below.
- Claims 4 and 11 have been canceled as listed below.
- Note: A full listing of all the allowed claims is indicated below.

Claims 1-14. (Canceled)

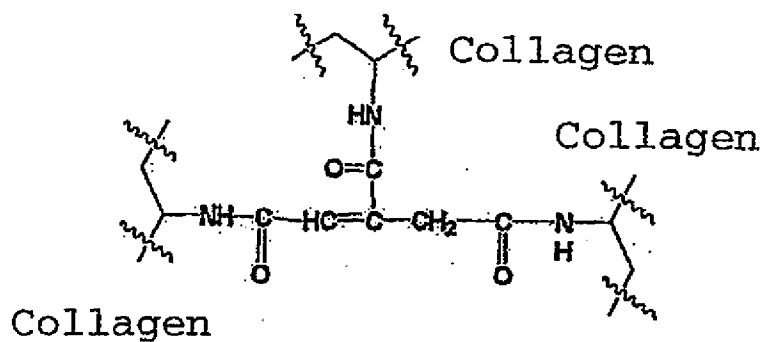
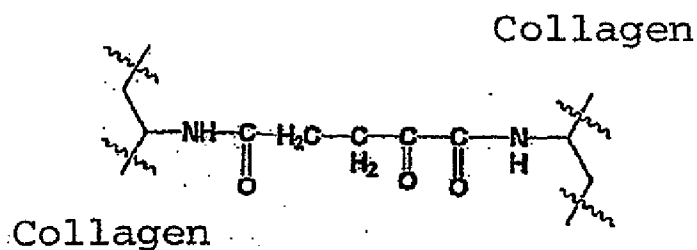
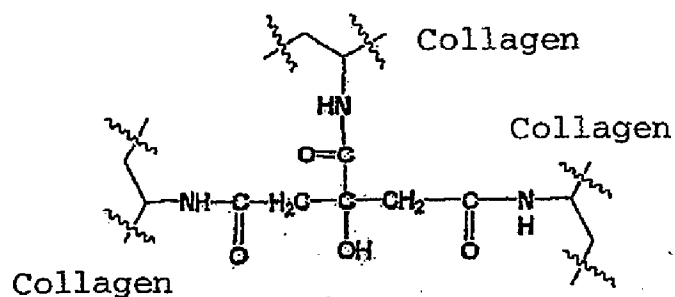
15. (Currently amended) A crosslinked high-molecular-weight product ~~according to claim 4,~~ obtained by crosslinking a high-molecular-weight compound with a biological low-molecular-weight compound, the crosslinked high-molecular-weight product comprising a gel that is metabolized *in vivo* after application *in vivo*, wherein the high-molecular-weight compound is collagen,

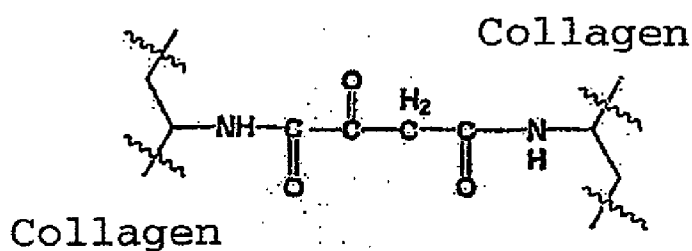
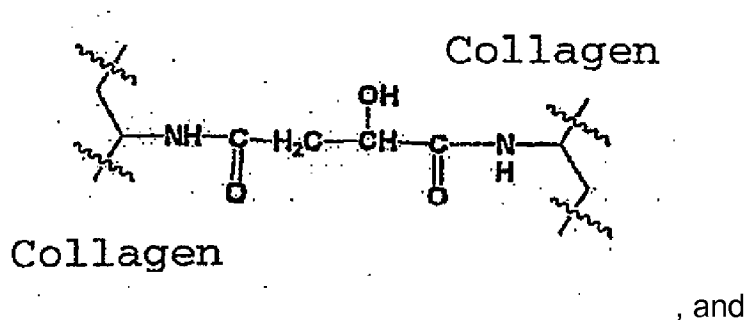
Art Unit: 1623

wherein the biological low-molecular-weight compound is obtained by modifying at least one carboxyl group of malic acid, oxalacetic acid, citric acid, *cis*-aconitic acid or 2-ketoglutaric acid with N-hydroxysuccinimide or N-hydroxysulfosuccinimide,

wherein the crosslinked high-molecular-weight product has a water content of 96 to 98%, and

wherein the crosslinked high-molecular-weight product has a chemical formula selected from the group consisting of:





16. (Currently amended) A method for producing a crosslinked high-molecular-weight product according to claim 11, comprising:

reacting 0.001 to 10 percent by weight of malic acid, oxalacetic acid, citric acid, or *cis*-aconitic acid with 0.001 to 10 percent by weight of N-hydroxysuccinimide or N-hydroxysulfosuccinimide in the presence of 0.001 to 20 percent by weight of carbodiimide at a reaction temperature of 0°C to 100°C for a reaction time of 1 to 48 hours to modify at least one carboxyl group of the malic acid, oxalacetic acid, citric acid *cis*-aconitic acid, or 2-ketoglutaric acid with N-hydroxysuccinimide or N-hydroxysulfosuccinimide to obtain a biological low-molecular-weight compound; and

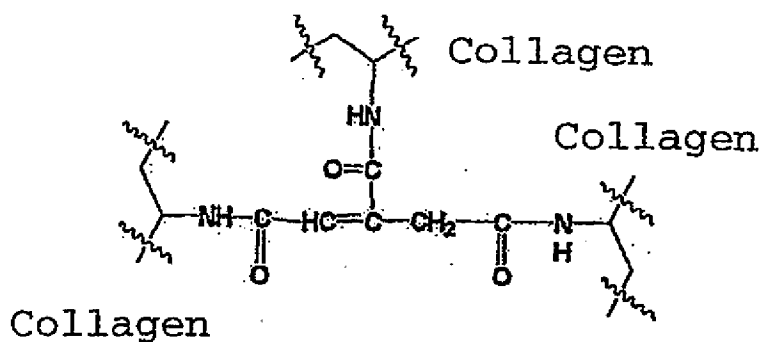
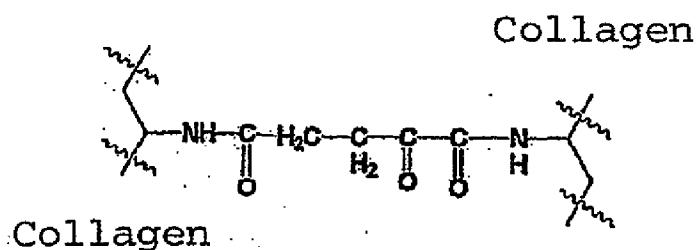
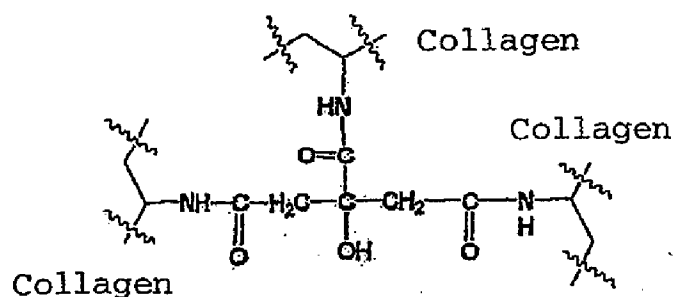
crosslinking a high-molecular-weight compound with the biological low-molecular-weight compound so as to yield a crosslinked high-molecular-weight product comprising a gel that is metabolized *in vivo* after application *in vivo*

Art Unit: 1623

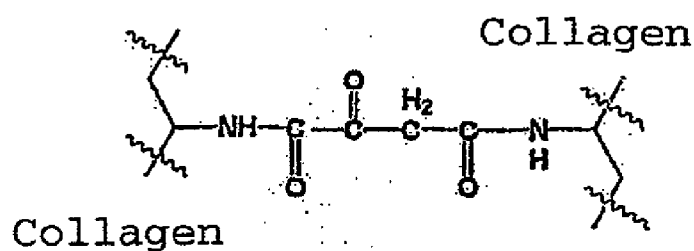
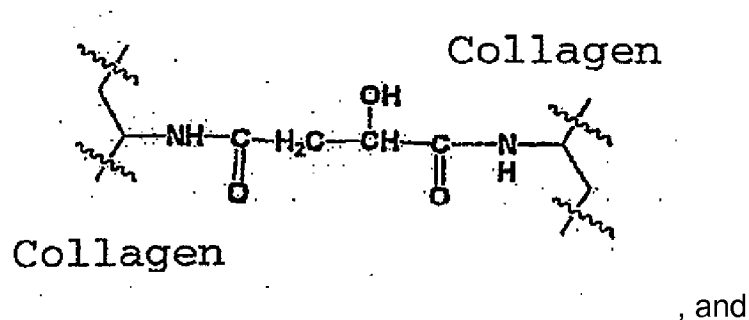
wherein the high-molecular-weight compound is collagen,

wherein the crosslinked high-molecular-weight product has a water content of 96 to 98%, and

wherein the crosslinked high-molecular-weight product has a chemical formula selected from the group consisting of:



Art Unit: 1623



DETAILED ACTION

Claims 15 and 16 are pending in the instant application and are seen to be allowable.

The Examiner's amendment is fully supported by the disclosure of the Specification as originally filed. For example, support for the amendments can be found in originally filed claims 1, 4, 7, 10 and 11, p. 3, line 24 to p. 4, line 3 of the Specification, and Tables 4 and 5 of the Specification. Furthermore, the Specification discloses examples for the method of making a crosslinked high-molecular-weight product as instantly claimed, as well as an analysis of the water content of the resultant product. Hence, the instantly claimed compounds and methods are enabled and have

sufficient written description in the Specification. The Examiner's amendment introduces no new matter.

The Declaration of Mr. Tetsushi Taguchi (inventor), submitted by Applicants on 18 November 2009 under 37 CFR § 1.132, is acknowledged and will be further discussed below.

Priority

This application is a National Stage entry of PCT/JP03/11669 filed on 1 November 2005 and claims priority to foreign application Japan 2002-265982 filed on 11 September 2002. A certified copy of the foreign priority document in Japanese has been received. An English translation of the foreign priority document, and a statement verifying the accuracy of the English translation, was received at the Office on 28 January 2010.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance: Applicants' crosslinked high-molecular-weight product and methods for making the crosslinked high-molecular-weight product, as recited in the instant claims, are not found to be taught or fairly suggested in the prior art, as discussed below. Thus, the claimed compounds and methods are seen to be novel and non-obvious over the prior art, as discussed below.

Applicants' arguments and amendments, filed 18 November 2009, and the Declaration of Mr. Tetsushi Taguchi, submitted by Applicants on 18 November 2009 under 37 CFR § 1.132, with respect to the rejection of claim 4 under 35 USC § 103(a), as being unpatentable over JP 2000-212286 by Nagura *et al.*, have been fully considered and are persuasive in view of the Examiner's amendment above. The Declaration shows that the biodegradable crosslinked high-molecular-weight products obtained by Nagura *et al.* do not have a water content of 96 to 98%, as instantly claimed. Furthermore, one of ordinary skill in the art would have no motivation to modify the biodegradable crosslinked high-molecular-weight products to achieve such a water content. Thus, this rejection is withdrawn.

Applicants' arguments and amendments, filed 18 November 2009, and the Declaration of Mr. Tetsushi Taguchi, submitted by Applicants on 18 November 2009 under 37 CFR § 1.132, with respect to the rejection of claim 11 under 35 USC § 103(a), as being unpatentable over JP 2000-212286 by Nagura *et al.*, further in view of Hermanson, have been fully considered and are persuasive in view of the Examiner's amendment above. The Declaration shows that the biodegradable crosslinked high-molecular-weight products obtained by Nagura *et al.* do not have a water content of 96 to 98%, as instantly claimed. Furthermore, one of ordinary skill in the art would have no motivation to modify the methods to obtain biodegradable crosslinked high-molecular-weight products having such a water content. Hermanson teaches methods for

Art Unit: 1623

crosslinking proteins and/or small molecules. The teachings of Hermanson do not remedy the deficiencies of Nagura *et al.* Thus, this rejection is withdrawn.

In view of the cancellation of claims 4 and 11, all rejections made with respect to claims 4 and 11 in the previous Office Action are withdrawn.

More specifically, the provisional rejection of claim 4 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending U.S. application no. 10/543,156, is hereby withdrawn. Insofar as the rejection would have been applicable to the instant claims, since the instant application is the earlier-filed application, this rejection is withdrawn. Furthermore, Applicants have indicated that they have abandoned U.S. application no. 10/543,156 by not filing a reply to the outstanding Office Action, dated 23 April 2009, in that application.

The crosslinked high-molecular-weight products and methods for making the crosslinked high-molecular-weight products, as instantly claimed, is disclosed in the instant Specification. Furthermore, the examples of the instant Specification describe the methods in detail, and also characterize the water content of the resultant crosslinked high-molecular-weight products. Hence, the compounds and methods are enabled and have sufficient written description in the Specification.

Accordingly, the Examiner's Amendment is sufficient to place the application in condition for allowance.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623

SCARLETT GOON
Examiner
Art Unit 1623